

2012

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Recommended Citation

Frøkjær B, Bolvig T, Griese N, Herborg H, Rossing C. Prevalence of drug-related problems in self-medication in Danish community pharmacies. *Inov Pharm*. 2012;3(4): Article 95. <http://pubs.lib.umn.edu/innovations/vol3/iss4/6>

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Prevalence of drug-related problems in self-medication in Danish community pharmacies

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Conflict of interests: The authors declare no conflict of interests.

Key words: drug-related problems; community pharmacy; OTC medicines; survey; counselling; interventions; frequency; pharmacy practice; self-medication.

Abstract

Background: Drug-related problems are known to be a major problem associated with pharmacotherapy. A broad range of studies, mainly in the area of prescription-only medicines, supports this fact. Only a few studies have evaluated drug-related problems with over-the-counter medicine and the role of community pharmacies in this.

Purpose: To quantify drug-related problems in self-medication (use of over-the-counter medicine) identified by community pharmacies in Denmark and to document the interventions by pharmacy staff in relation to the identified drug-related problems.

Method: A descriptive study mapping drug-related problems in self-medication registered at the counter at a selected number of Danish community pharmacies.

Results: Data for 3,868 consecutive customers with requests for over-the-counter (OTC) medicines were registered at 39 community pharmacies. The pharmacies registered a total number of 4,324 OTC medicines requests, illustrating that a customer requested 1.1 OTC medicines on average. Drug-related problems (DRPs) were identified for 813 customers, equivalent to DRPs for 21.0 % of all customers, presenting symptoms or requesting OTC medicines, and for 20 % of all over-the-counter medicines requests. 1,239 DRPs were registered, corresponding to an average of 1.5 DRPs per customer requesting OTC medicines.

Community pharmacies estimated that they solved or partly solved 76.2 % of the detected DRPs; 73 % were solved without involving a general practitioner.

Conclusions: DRPs were identified for 21.0 % of the pharmacy customers presenting a symptom or asking for an OTC medicine. The community pharmacy counselled the customers with DRPs more thoroughly than other customers by giving 2.4 pieces of professional advice, compared to an average of 2.1 to customers in general. It is not possible to determine the magnitude of the safety risk involved. Based on the most frequent categories of DRPs, there were risks of insufficient effect, unintended effects and, to a lesser extent, inappropriate self-medication.

Introduction

Drug-related problems (DRPs) are known to be a major problem associated with pharmacotherapy²⁻⁴. A broad range of studies, mainly in the area of prescription-only medicines, supports this fact⁵⁻⁹. A DRP has been defined by Hepler and Strand as: "A drug-related problem is an event or circumstance involving drug treatment that actually or potentially interferes with the patient's experiencing an optimum outcome of medical care". There are few Danish studies on DRPs: Danish pharmaceutical care research projects documented DRPs for asthma patients and for the elderly, and later, a Danish study documented DRPs in general practice¹⁰⁻¹². Elderly citizens living in nursing homes have been in focus in several Danish research projects, concentrating on ensuring an effective handling of DRPs¹³⁻¹⁵.

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Only a few studies have evaluated DRPs with OTC medicines and the role of community pharmacies in preventing or resolving these problems¹⁶⁻²⁰.

Denmark has a population of 5.4 million people, who are served by 314 pharmacies, corresponding to 17,200 inhabitants per pharmacy. A pharmacy is obliged to provide all pharmacy-restricted medicines, regardless of whether they are on prescription or not. In practice, this means that the pharmacy must have any medicine requested in stock or be able to deliver it within 24 hours. Since October 2001, other outlets like supermarkets and kiosks have been permitted to sell a selection of OTC medicines¹.

In Denmark, community pharmacies are the primary source of OTC medicines¹. OTC medicines at the pharmacy are only available on request at the counter, and not via self-service. Apart from the medicines supply, Danish community pharmacies are responsible for providing information and counselling to ensure a safe drug use. Pharmacies also provide pharmaceutical care and preventive services,

contributing to health promotion, ill-health prevention, self-care, and the appropriate use of drugs. Community pharmacies keep information on prescription medicines for their customers, but not on OTC medicines.

Over the last decade, there has been a development in Denmark towards deregulation making the access to OTC medicines easier for the public¹. Starting in October 2001, other outlets (e.g. supermarkets and kiosks) have been permitted to sell a selection of OTC medicines. The total consumption of OTC medicines did not change despite the increased number of outlets. The pharmacies' share (in DDD) of the OTC medicines was 83 % in 2010²¹.

However, when buying OTC medicines from other outlets than pharmacies, the only information and counselling customers get is the information written on the package, as unskilled staff are not allowed to give information on medicines. This underlines the importance of pharmacy staff giving professional advice to OTC customers.

A British article raised the awareness to safety issues of OTC medicines saying that the public needs to be aware that OTC medicines should be treated with the same care as prescribed medicines, and that advice on recommended dose, contraindications and interactions should be adhered to²².

Several examples of studies of counselling on OTC medicines^{23;18;24} were made in Sweden:

One study concluded that a counselling model designed to discover and resolve problems related to symptoms and drug use appeared to have a favourable impact on outcomes in customers with dyspepsia seeking non-prescription drug treatment in Swedish pharmacies²³. A parallel Danish intervention study showed similar results for dyspepsia and hay-fever customers¹⁶. Another Swedish study demonstrated a need for more professional attention and intervention by pharmacy staff to prevent and rectify DRPs for non-prescription consumers. It was particularly important to make sure that consumers receive the appropriate drugs for their current ailments¹⁸. It was also found that counselling was a means to improve drug use, when it came to prescription-only medicines. More DRPs were found in patients sending a representative to pick up their medicines than in patients visiting the pharmacy themselves²⁵.

In a German study with 11,069 pharmacy customers, a direct pharmacist-patient interaction about self-medication revealed relevant DRPs in nearly 1 out of 5 encounters. Approximately 75 % of the customers requested a specific OTC medicine. In these cases, the majority of DRPs was identified (80 %). The most frequent DRPs were:

inappropriate self-medication, inappropriate requested drug, too long duration of drug use (including abuse), and wrong dosage¹⁷.

The frequency and distribution of DRPs among Danish pharmacy customers is unknown. Hence this project was inspired by the German study, which described the nature and frequency of DRPs in self-medication (OTC drugs) in daily community pharmacy practice in Germany¹⁷. In order to allow for comparison of results, a similar method with similar documentation forms was used.

Purpose

The purpose of the study was:

- to provide a quantitative description of the nature and frequency of drug-related problems in self-medication as identified by community pharmacies in Denmark
- to document the interventions by pharmacy staff in relation to the identified drug related problems

Method

The project was designed as a descriptive study performed at a convenience sample of Danish community pharmacies, mapping DRPs registered at the pharmacy counter when selling OTC medicines.

At each pharmacy two staff members (at least one pharmacist, and possibly a pharmaconomist¹) were trained in the registration process in order to ensure a consistent documentation. The training was based on the registration of five test cases, followed up by a problem-solving conference call (four pharmacies at a time with two researchers). Following the training period, the pharmacists were instructed to register 100 consecutive customers with an OTC request per pharmacy.

The registration was electronic, using a link to the Intranet, a programme available at all pharmacies.

Setting and study population

The study was conducted in June and July 2011 in Danish community pharmacies. Pharmacies were invited to join the project via an announcement on the website of the Association of Danish Pharmacies in April 2011. Participation was optional. However, as this did not provide a sufficient number of pharmacies, a telephone follow-up was initiated. Each participating pharmacy provided two employees (at least one pharmacist and possibly a pharmaconomist).

¹ Pharmaconomist corresponds to pharmacy assistant²⁶

The participation of pharmacies was financially compensated to the participating pharmacies by the Association of Danish Pharmacies (with 3,000 DKK, corresponding to approx. 400 EUR). The compensation was given after data had been received at Pharmakon.

The pharmacies were instructed each to register 100 consecutive customers, a strategy used to avoid bias in the selection of customers. A customer would be included when asking for an OTC-medicine or presenting a symptom or a problem. Data was registered immediately after the dialogue with the customer.

The staff members were trained in identifying and documenting DRPs, based on the quality standard applying for counselling at the counter, and in electronic registration of data. The standard follows The Danish Healthcare Quality Programme²⁷. The project had a website, available via a link to the Intranet, and a programme available at all pharmacies for the distribution of documents and for the registration of data. Videos demonstrating advice-giving at the counter and the registration of data were available at the same website as well as five cases intended for training to make implementation of the process uniform in all pharmacies. The participating pharmacists and pharmaconomists prepared themselves by working on these cases. Following the training period, a series of conference calls were organized, each with ten participants, including two researchers from Pharmakon as moderators. Extracts from the conference calls were distributed to the participants afterwards.

Data collection and analysis

An electronic registration form was developed for the project, using the same SharePoint platform as used for the pharmacies' intranet sites.

The registration form was inspired by the German registration form¹⁷. Documentation included data on patient characteristics (e.g. estimated age, gender, availability of a patient file including drug history in the pharmacy), and the nature of the OTC request (e.g. symptom presentation, OTC medicine request, first-time or repeat request, indication). If one or more DRPs were detected, the nature and solution of each DRP were recorded; the most frequent DRPs, interventions, and problem solutions were provided as check boxes on the form. Pharmacists were requested to document other DRPs, interventions, and solutions not provided as check boxes in free-text fields. Furthermore, the time needed for solving the problem was recorded. In the development phase, contact was taken to the German researchers as well as to the Association of Danish Pharmacies concerning the phrasing of some of the questions in order to ensure high

validity. This was in particular applicable with respect to the categories of symptoms, the DRPs and the interventions by the pharmacy staff. The registration form was tested in the training phase, and minor corrections were made. Only customers requesting OTC medicines or presenting symptoms for themselves or for their children (under the age 15) were included in the study.

Registrations were made on the basis of each OTC request. Up to three OTC requests could be registered for one single customer. Data were transferred from the registration form to an Excel file and later on to SPSS (Version 19). A random quality check was performed on the registrations. Data were analyzed in SPSS as crosstabs and frequencies. No statistical tests were performed.

Results

Data were collected from 39 community pharmacies (out of a total of 314 community pharmacies, corresponding to 12.5 %²⁸). They documented data from 3,868 customers with a total of 4,324 OTC requests, corresponding to each customer having 1.1 OTC requests. See details in Table 1.

Gender and age

Gender and age were registered for 3,765 customers. 2,409 (64.0 %) were female, and 1,356 (36.0 %) were male. Almost 2/3 of all customers in the survey were between 21 and 64 years old. More than every third customer was in the age group 41-64 years (35.2 %). In 10.4 % of requests, the OTC medicines requested were for children.

OTC requests and customers' experiences

It was registered whether customers presented a symptom or requested an OTC-medicine. Customers were asked if they had any experience with the requested OTC-medicine, and whether it was a first-time request or not. It should be noted that the sum of requests is higher than the number of customers, thus explaining that the percentages of customers are >100 % in Table 2.

The results showed that 85.1 % of the customers were frequent users, which meant that the customers had bought the medicine at least once before. They also showed that 78.3 % asked for a specific OTC medicine, and that only a minor part presented a symptom (6.8 %). Slightly more than 1/4 of the customers were first-timers with regards to the actual treatment (26.8 %). Half of the first-timers presented a symptom, and half requested an OTC- medicine (13.8 % and 13.0 % respectively).

Prevalence of DRPs

DRPs were registered for 813 customers (out of the total number of 3,868 customers in the survey), which corresponds to 21.0 % of all customers.

The survey documented 1,239 DRPs for 813 customers, corresponding to an average of 1.5 problems for a customer with DRP, as 7.3 % of the customers had more than one DRP.

The survey documented 4,324 OTC requests and 842 DRPs, corresponding to DRPs for 19.7 % of the OTC requests.

Presented symptoms

Symptoms presented, or symptoms for which the requested OTC-medicine was intended to treat were registered. If the customer had more than one OTC request, the symptom for each OTC request was registered. Symptoms were registered for 2,912 customers in the survey.

Customers with DRPs had symptoms similar to customers' without DRPs. Pain was by far the most frequent symptom and was registered with more than half of the customers in the survey (57.6 %). The second most frequent symptom was allergy or hay fever, which was registered for almost every fifth customer (16.7 % of all customers). Data were registered in June/July, a period with a relatively high pollen occurrence in Denmark, which influences the prevalence of symptoms. Pain and allergy/hay fever together were the symptoms presented by nearly 3/4 of all customers in the survey. Customers with allergy or hay fever tended to have more DRPs (20.3 %) than all customers in the survey (16.7 %).

Types of DRPs

Table 2 shows an overview of the types of DRPs identified in the study.

The results showed that the most frequent DRP was: "Choice of self-medication is not appropriate/optimal for the condition". This problem was registered 364 times and for almost half of the customer with DRPs.

The second most frequent DRPs were documented for 10 to 20 % of customers with a DRP: "Too little of the drug is being taken", "The drug is taken for too long (dependency)" and "Adverse drug events".

Pharmacy interventions

Pharmacy staff registered interventions (including counselling) in relation to each customer, presenting a DRP or not. More than one intervention could be registered, if appropriate.

Figure 1 shows the pharmacy interventions. It shows a higher frequency of interventions for customers with DRPs.

"Counselling on self-medication", which according to the instruction covered optimal choice and use of the OTC medicines, was the most frequent intervention and was given to almost 3/4 (73.5 %) of all customers. For customers with DRPs it was given to 87.5 %.

"Referral to General Practitioner (GP)" (covers direct referral as well as conditional referral) was given more frequently to customers with DRPs (35.2 % versus 10.7 %). The intervention "Recommendation of another drug" was given to 23.0 % of customers with DRPs and to 6.7 % of other customers.

Solving DRPs

The pharmacy staff estimated whether the DRP was solved, partly solved, or not solved.

Pharmacists solved or partially solved DRPs for 90.5 % (76.2 + 14.3) of all OTC customers and for 78.0 % (45.6 + 32.4) of customers with DRPs.

The results showed that 73 % of the DRPs were solved by the pharmacy staff without consulting the GP and that 35.2 % of the customers with DRPs were referred to a GP.

It should be noted that pharmacy staff responded in general to how they had contributed to overall problem solving, no matter whether a DRP was identified or not.

By comparing counselling and DRPs it appeared that the problem: "The choice of self-medication is not appropriate", the most frequent solution was "Counselling on self-medication". "Too low dosage" was solved by counselling on self-medication or by suggesting another drug. When a customer experienced side-effects, the pharmacy staff counselled on self-medication or referred to the general practitioner, possibly replacing the drug in question. In case of the DRP: "The drug is taken for too long (dependency)", the pharmacy staff counselled on self-medication and self-care and provided written information.

Discussion

DRPs were identified for 21.0 % of OTC-customers and for 20.0 % of all OTC requests. On average, a customer with a DRP had 1.5 DRPs. In the German study, DRPs were identified in 17.6 % of all self-medication requests and in 18.3 % of all patients¹⁷. In both countries there was only a small difference in the result per customer and the result per drug request. The frequency of DRPs is slightly higher in Denmark than in Germany, but the overall level was similar. Both studies underline that self-medication is frequently associated with risks.

The most frequent DRPs were: "The choice of self-medication is not appropriate/optimal for the condition" in 44.8 % of the DRPs; "Too little of the drug is being taken" in 17.0 %; "The drug is taken for too long (dependency)" in 15.0 %, and "Adverse drug events" in 13.8 %. We see similarities to the German study where the most frequent DRP is "Self-medication inappropriate" (29.7 %), "Requested drug inappropriate" (20.5 %) and "Intended duration of drug use too high" (17.1 %) ¹⁷. The figures are, however, not directly comparable as the Danish figures are % per customer and the German are % per request.

The most frequent symptom was pain (57 % of all customers). The most frequent DRPs in this group were the same problems as mentioned above, and this result is very similar to the German study where pain, and respiratory and gastrointestinal complaints were the most frequent indications ¹⁷. The second most frequent symptom was allergy/hay fever. This is probably due to seasonal variations as our data were collected in June/July, a time of the year with much pollen. The German study was performed in August and September, and here allergy was ranked 12 on the list of distribution of DRPs by indication. The phrasing of the question of the Danish questionnaire was, however, modified in comparison to the German due to the malfunctioning of some of the questions in the German questionnaire ¹⁷. Direct comparison is, therefore, not possible on this issue.

For customers with DRPs, 78 % of the DRPs were partly or completely solved, and 73 % of these were solved without involving a GP. The German study reported a higher level of problem solving. DRPs were solved for 44.9 % or partly solved for 45.3 % of all DRPs ¹⁷. The Danish pharmacy staff reported that this question was difficult as they lacked factual information and in many cases the response was an estimation of a future effect. This is to be expected as we are dealing with a question concerning the future. Data are self-reported, which gives a potential risk of bias, especially as regards questions involving estimation. This is in particular an issue with respect to pharmacy staff's estimating whether the problem was solved, partly solved or not solved.

The study design implied that the pharmacies should register 100 consecutive customers; all requests for OTC-medicines should be registered (up to a maximum of three requests/customer) for these 100 customers. This design was chosen to avoid selection bias and ensure that the study population was representative of the general population. Of the study population, 64 % were female, 65 % were between 21 and 64 years old, and 20 % were 65 or older.

The statistics from the Association of Danish Pharmacies report that 79 % of all customers are prescription customers and of these 56 % are female and 48 % are between 20 and 64 years old, 45 % are 65 or older. Comparing the study population of OTC-customers to pharmacy customers in general, reveals that the survey included younger people and more female. The data from the Association of Danish Pharmacies, however, does not include information on gender and age for OTC customers (21 % of all customers) hence no direct comparison is possible ²⁹.

Both the Danish and the German study confirm UK studies finding that OTC medicines should be treated with the same care as prescribed medicines ²². Pharmaceutical counselling is an important instrument for assuring treatment appropriateness and safety of OTC drugs, and it is recommended to introduce quality assurance for counselling ⁹.

A recent Swedish survey on the sale of non-prescription medicines inside and outside a pharmacy concludes that in many cases, counselling is incomplete or directly incorrect from both places. Ignorance about the differences between different types of pain killers can lead to the wrong choice of drugs and to an increased risk of adverse effects. There are gaps in the knowledge of what an employee outside pharmacies may say or not say to a client about a drug. The editor recommends that outlets which sell medicine continuously educate their staff in what they can say and not say about a drug, and when to refer to a pharmacist ³⁰. Our study does not describe the situation in outlets outside community pharmacies, and hence it may not be representative for the total frequency of DRPs in relation to OTC medicines in Denmark. Based on the Swedish findings it can be anticipated that there is less help for resolving DRPs outside the pharmacies.

The results document the importance of having focus on counselling in relation to OTC medicines. It is recommended in the Swedish report that other medicine outlets than pharmacies refer customers to a pharmacy or a general practitioner when a medical condition is presented to them. This underlines that pharmacy is in a unique position for this counselling and should make use of that for the sake of patient safety.

Conclusions

DRPs were identified for 21 % of the pharmacy customers presenting a symptom or asking for an OTC medicine. The frequency of DRPs was slightly higher in Denmark than in Germany (18 %), but the overall level was similar. Both

studies document that self-medication is frequently associated with risks.

It is not possible to determine the magnitude of the safety risk involved. Based on the most frequent categories of DRPs, there were risks of insufficient effect, unintended effects and, to a lesser extent, inappropriate self-medication.

Both the Danish and the German study documented that community pharmacies are in a unique position for counselling on self-medication. Pharmacies should focus on this role for the sake of patient safety.

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Table 1: Basic study data: Numbers and percentages of total number of customers

Study period	June - July 2011
Community pharmacies,	39
Customers,	3,868
Documented OTC requests	4,324
Documented DRPs	1,239
OTC requests with a DRP, n=842	19.7 %
Customers with a DRP, n=813	21.0 %
Customers, n	
with one DRP	488
with two DRPs	259
with three DRPs	40
with four DRPs	21
with five DRPs	2
with six DRPs	3
Customer's gender, n (%)	
Female, n=2409	64.0 %
Male, n=1356	36.0 %
Estimated age group (years) of customers, n (%)	
0-15, n=398	10.4 %
16-20, n=187	4.9 %
21-40, n=1,145	29.8 %
41-65, n=1,353	35.2 %
> 65, n=759	19.8 %
Symptom presentation, n=777	20.6 %
OTC medicine request, n=3,451	91.3 %
First-time request, n=1,011	26.8 %
Repeat request, n=3,217	85.2 %
Result of intervention, n (%)	
DRP solved, n=343	45.6 %
DRP partially solved, n=244	32.4 %
DRP do not know if the problem is solved, n=81	10.8 %
DRP not solved, n=84	11.2 %

Table 2: Types of DRPs registered for customers with DRPs and for all customers

DRP	Number of DRPs registered	% of customers with DRP n=813	% of all customers n=3,868
Choice of self-medication is not appropriate/optimal for the condition	364	44.8	9.4
Too little of the drug is being taken	138	17.0	3.6
The drug is taken for too long (dependency)	122	15.0	3.2
Adverse drug events	112	13.8	2.9
Too much of the drug is being taken	66	8.1	1.7
Double medication	60	7.4	1.6
The drug is taken for too short a time	44	5.4	1.1
Wrong use of the drug (technically)	43	5.3	1.1
Interaction with other medicine	40	4.9	1.0
Contraindication	35	4.3	0.9
Other (not appropriate, problem in drug use)	215	26.4	5.6
SUM	1,239		

Figure 1: Counselling Interventions

